Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 60 FR 65350, December 19, 1995) is amended to reflect the realignment of the Office of Health and Industry Programs, Center for Devices and Radiological Health (CDRH), Office of Operations, in the Food and Drug Administration (FDA).

The Immediate Office of the Director, Office of Health and Industry Programs will consist of two new staffs; the Regulations Staff and the Staff College. CDRH believes that the establishment of these two new staffs within the Immediate Office of the Director, Office of Health and Industry Programs, will increase visibility to important program areas of the Center.

Under section HF–B, Organization:

1. Insert the following new subparagraphs under paragraph *Office of Health and Industry Programs (HFWG), Center for Devices and Radiological Health (HFW)*, reading as follows:

Program Operations Staff (HFWG–1). Provides all necessary administrative support to the Office.

Provides services to track the status of on-going Office programs as well as all incoming and outgoing congressional and FDA or Center-tracked correspondence.

Provides personnel computer support to Office staff including the evaluation of hardware and software, installation of hardware and software and assistance in resolving hardware and software problems.

Responds to public and government requests for information about medical device and radiation-emitting products. Serves as the Center Consumer Affairs Representative.

Regulations Staff (HFWG–2). Advises the Center Director and appropriate Agency officials on FDA regulation development responsibilities relating to medical devices and radiological health activities. Serves as the Center focal point for liaison on regulations development activities with the Office of Chief Counsel.

Coordinates the development, review and submission of Federal Register publications for the Center. Prepares position statements for the Center on standards promulgated by other organizations.

Staff College (HFWG–3). Develops necessary training courses for Center employees by providing continuing education credits for selected programs; providing live satellite teleconferences and distance learning telecasts; and coordinating and sponsoring a variety of seminars and lectures.

Performs needs assessments and develops training objectives. Designs courses and course evaluations.

2. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: December 13, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

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Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Black Lung Clinic Program Regulatory Requirements (42 CFR 55a) (OMB No. 0915–0081) Extension/No Change—The purpose of the Black Lung Clinics Program (BLCP) is to stimulate and encourage local public and private agencies to improve the health status of coalworkers and to increase coordination with other programs to assist the coalworkers population. The goal of the BLCP is to provide services to minimize the effects of respiratory and pulmonary impairments of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improve the functional status, i.e., ''quality of life'', of the miner and reduce economic costs associated with morbidity and mortality arising from pulmonary diseases.

This request is for approval of the reporting and recordkeeping requirements in program regulations as follows:

1. 42 CFR 55a.201 and 55a.301—Reporting—Grantees must submit applications for continued grant support. The regulations outline the requirements for grant applications for States (55a.201) and for entities other than States (55a.301).

2. 42 CFR 55a.201 (a) (3)—Recordkeeping—The regulations require that grantees conduct outreach to active and inactive miners, which requires maintenance of a register of persons with pulmonary impairments.

3. 42 CFR 55a.201 (a) (4)—Recordkeeping—The regulations require that individual patient care plans be provided for all patients. This includes development and periodic updating of the patient plans.

Estimates of annualized hour burden are as follows:

Regulatory requirement [1]	Number of record-keepers	Annual hours per record-keeper	Total burden
55a.201(a)(3)—patient registry	14	357	5,000
55a.201(a)(4)—development of patient plans	14	1,214	17,000